[redacted]

From: [redacted]
Sent: 23 March 2017 11:40
To: [redacted]
Cc: Woolley, Dr Jane
Subject: RE: finasteride variation confidential

Hi [redacted]

Thanks for letting me know.

I'll start working on proactive comms for the healthcare professionals you've listed below. I'll also prep some reactive lines in case this is picked up by general media.

[redacted]

From: [redacted]
Sent: 23 March 2017 11:05
To: [redacted]
Cc: Woolley, Dr Jane
Subject: RE: finasteride variation confidential

Dear [redacted]

The company have submitted the paperwork for the variation to include the following information:

Patient Leaflet

The following additional information will be added to patient information leaflet:

Warning and precautions:
Mood alterations and depression
Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with Propecia. If you experience any of these symptoms stop taking Propecia and contact your doctor for further medical advice as soon as possible.

In section 4: **Possible side effects**
'Depression' with a frequency of 'Uncommon: may affect up to 1 in 100 people'

The Summary of Product Characteristics, which is orientated primarily towards health professionals, will be updated as follows:

Section 4.8 **Undesirable effects**
Depressed mood will be changed to 'depression' (frequency *Uncommon*)

A warning will be added in section 4.4 **Special warnings and precautions for use**:
Mood alterations and depression
Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with finasteride 1 mg. Patients should be monitored for psychiatric symptoms and if these occur, treatment with finasteride should be discontinued and the patient advised to seek medical advice.

The updated advice will also be cascaded by National Competent Authorities throughout Europe.

In the UK we will cascade information through a Drug Safety Update article which we will publish on our website. The article containing a link to report suspected adverse reactions will, in addition, be proactively cascaded to healthcare professionals working in the areas of Dermatology, Psychiatry and Endocrinology.
We plan to publish the article in the next issue. A link can be found here:
https://www.gov.uk/drug-safety-update

Please do not release this externally until the variation has been finalised. I will contact you when it has concluded (After next Thursday, I'm on holiday during the first two weeks of April until the 18th – so it's unlikely that I'll contact you before then).

Please let me know if you need any additional information.

Kind regards
[redacted]

From: [redacted]
Sent: 21 March 2017 11:34
To: [redacted]
Cc: Woolley, Dr Jane
Subject: RE: finasteride variation

Thanks [redacted]

From: [redacted]
Sent: 21 March 2017 10:37
To: [redacted]
Cc: Woolley, Dr Jane
Subject: RE: finasteride variation

Dear [redacted]

The final decision has been circulated by the Reference Member State (see attached) and apparently the company have seven calendar days to respond to that position. We will, therefore, know by the 27th or 28th March what the company position is and whether the product information will be updated as suggested.

I will let you know when I know more.

Kind regards
[redacted]

From: [redacted]
Sent: 20 March 2017 12:14
To: [redacted]
Cc: Woolley, Dr Jane
Subject: RE: LTT - AlteplaseFrom

Hi [redacted]

Is there any update on finasteride?

Thanks,
[redacted]

[redacted]